

Educational interventions to improve self-care and reduce self-neglect in Iranian elderly people with diabetes

Submission date 24/09/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 28/09/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 17/06/2024	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Due to the increase in life expectancy, management of diabetes is very important and older diabetics should be able to take care of themselves to prevent or delay the complications of diabetes. The self-care deficit in elderly people with diabetes is due to an irreversible decrease in physical and cognitive function, and elderly people with diabetes have more cognitive problems than healthy individuals due to defects in memory and executive function. Mindfulness interventions can help change erroneous thoughts and behaviour patterns and a self-regulatory approach can empower the elderly in a step-by-step manner. The impact of mindfulness interventions or self-regulatory interventions has been examined separately but the effect of a combination of mindful self-care and self-regulation interventions has not been examined until now. The aim of this study is to compare the effect of self-regulatory intervention programs only with a combination of mindful self-care and self-regulation interventions on self-care, self-regulation, mindful self-care, and self-neglect in elderly people with diabetes.

Who can participate?

Community-dwelling elderly people aged 60-80 years with diabetes

What does the study involve?

First, participants are selected from three centers that are randomly selected by simple random sampling. Each center is assigned to one intervention group and the number of participants in each center is 45. Seniors fill out five questionnaires, and then the daily training starts via WhatsApp and lasts for 2 months. After 4 weeks testing is performed and after 16 weeks a follow-up is performed.

What are the possible benefits and risks of participating?

Interventions improve self-care in the elderly and are not harmful.

Where is the study run from?

Shiraz University of Medical Sciences (Iran)

When is the study starting and how long is it expected to run for?
February 2020 to July 2021

Who is funding the study?
Shiraz University of Medical Sciences (Iran)

Who is the main contact?
1. Dr Mohammad Hossein Kaveh, mhkaveh255@gmail.com
2. Mohadeseh Motamed-Jahromi, mohadesehmotamed@gmail.com

Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

19030

Study information

Scientific Title

Designing and evaluating educational interventions based on mindfulness and/or self-regulation in improving self-neglect and self-care in elderly people with diabetes in Shiraz

Study objectives

Do educational interventions based on mindfulness or self-regulation affect the improvement of self-neglect and self-care of the elderly with diabetes in Shiraz, Iran?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 26/02/2020, Shiraz University of Medical Sciences Research Ethics Committee (Floor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafashan & South Falamak, Qods Town, Tehran, Iran; +98 (0)21 81455618; ethics@behdasht.gov.ir), ref: IR.SUMS.REC.1398.1365

Study design

Three-arm cluster randomized controlled trial

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

Community

Study type(s)

Quality of life

Participant information sheet

No participant information sheet available

Health condition(s) or problem(s) studied

Community-dwelling elderly people with diabetes

Interventions

This study was conducted over 24 weeks at three Urban Health Centers in Shiraz, Iran. Among the urban health centers with the most people with diabetes, three centers were randomly selected and then the centers were randomly assigned to the intervention and control groups. The elderly who were eligible were identified and 45 people in each center were selected using a list of random numbers.

Due to the prevalence of COVID-19, the training was done through WhatsApp software. Three WhatsApp groups were formed to provide training to the participants. In all three groups, training content was sent daily to participants for the first 2 months, and for the next 4 months training continued only on Mondays. Messages were sent in the form of text, images, media, audio, images, emoticons, and links. Data were collected between December 2020 and May 2021. In the first arm, a self-care training program focused on behavior change based on self-regulatory theory was sent. In the second arm, a combined intervention was presented that included mindful self-care training and a self-care training program based on self-regulatory theory. In the control arm (CO), COVID-19 prevention training was sent to the participants. Five questionnaires including demographic information, summary of diabetes self-care activities (SDSCA), the mindful self-care questionnaire (MSCS), Elder Self-Neglect Scale (ESNS), and Short form Self-Regulation Questionnaire (SSRQ) were used. Information from telephone interviews was collected at baseline, week 4, and week 16 after the intervention programs.

Intervention Type

Behavioural

Primary outcome measure

Measured at baseline, week 4, and week 16 after intervention programs:

1. Demographic information collected using a researcher-made questionnaire that included gender, age, marital status, education level, occupational status, living arrangement, duration of diabetes, other diseases
2. The different activities of diabetic patients during the previous 7 days measured by a 12-item self-report scale: Summary of Diabetes Self-Care Activities (SDSCA)
3. Mindful self-care assessed using the mindful self-care scale (MSCS). This instrument measures the frequency of behavior within the past week in six subscales: mindful relaxation, physical care, self-compassion, and purpose, supportive relationships, supportive structure, mindful awareness, and three general items
4. Elder self-neglect measured by the Elder Self-Neglect Scale (ESNS) developed by the researchers. It consists of 26 items that specified the frequency of the self-neglect behaviors.
5. Self-regulation behavior in elder diabetics measured by the Short form Self-Regulation Questionnaire (SSRQ). It included 31 items that the higher the scores indicate a better level of self-regulation

Secondary outcome measures

There are no secondary outcome measures

Overall study start date

26/02/2020

Completion date

30/07/2021

Eligibility

Key inclusion criteria

1. Age 60-80 years old
2. Type 2 diabetes (duration ≥ 6 months)
3. Sufficient ability to read and write
4. Sufficient activity daily living
5. Sufficient WhatsApp and Internet literacy
6. Smartphone and Internet access

Participant type(s)

Patient

Age group

Senior

Sex

Both

Target number of participants

135 elderly with diabetes, 45 participants in each group

Key exclusion criteria

1. Persistent serious psychological problem
2. Does not answer phone calls and messages more than three times
3. Reluctant to participate in the intervention

Date of first enrolment

15/11/2020

Date of final enrolment

15/07/2021

Locations**Countries of recruitment**

Iran

Study participating centre

Pardis Urban Health Center

Fars Province, Bahonar Underpass

Shiraz

Iran

71 9100 2030

Study participating centre

Vali-e-Asr Health Center

Fars Province, Sharak-e-Shahid Dr.Bahonar, Shah Gholi Beigi

Shiraz

Iran
71 3824 5884

Study participating centre
Ghotb Al Din Health Center
Fars Province, Fakhr Abad St
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Sponsor information

Organisation
Shiraz University of Medical Sciences

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Sponsor type
University/education

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ROR
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Funder(s)

Funder type
University/education

Funder Name
Shiraz University of Medical Sciences

Alternative Name(s)
SUMS

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

Iran

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

Intention to publish date

31/05/2022

Individual participant data (IPD) sharing plan

SPSS datasets without participants' names will send to academic readers after publishing the relevant articles if requested from Mohadeseh Motamed-Jahromi (mohadesehmotamed@gmail.com).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		15/06/2024	17/06/2024	Yes	No